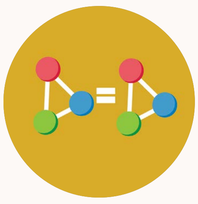
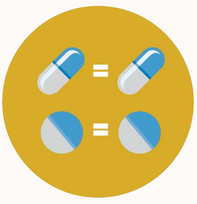
What Makes a Generic the Same as a Brand-Name Drug?

Pharmaceutical Equivalence

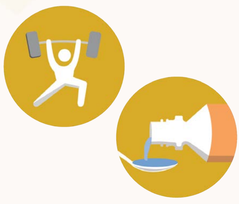
Lab test results and other documentation from the generic manufacturer are reviewed by FDA to demonstrate that:



The generic drug has the same active ingredient(s) as the brand-name drug.



The generic drug has the same dosage form as the brand-name drug.



The generic drug has the same strength and route of administration as the brand-name drug.

The generic drug has the same indications as the brand-name drug.

The inactive ingredients of the generic drug are safe and don't change how the drug works.

The generic drug will work as intended for a reasonable amount of time before expiring.

Bioequivalence

Comparisons—often in human volunteers who take both the generic and brand-name drugs—ensure that:

The generic drug performs the same in the human body as the brand-name drug.

The generic drug is as safe and effective as the brand-name drug.

Appropriate Container and Labeling

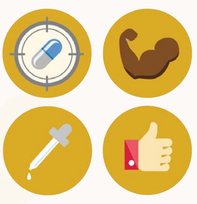
FDA inspection of the container and labeling demonstrates that:

The generic drug's label is the same as the brand-name drug's label, with some exceptions—such as indications protected by patents or exclusivity.

The generic drug is sold and shipped in an appropriate container.

Appropriate Manufacturing

FDA inspection of facilities demonstrates that:



The generic drug meets the same requirements for identity, strength, purity, and quality as the brand-name drug does.

The manufacturer is capable of making the generic drug correctly and consistently.

Visit www.FDA.gov/GenericDrugs to learn more.

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